

REMARKS/ARGUMENTS

Application Amendments

By the amendments presented, the specification is rewritten on Pages 21 and 25 to add (SEQ ID NO: 5) designations for the CPI3 peptide sequence listings set forth therein. Support for this designation of the sequences set forth is found in the originally filed specification, for example at Page 21, line 14.

Also by the amendments presented, Claim 1 is rewritten to characterize the claimed method as directed to the detection of the presence or absence of a bacterium in a sample "selected from a wound, a body fluid or fluid from a wound". Support for addition of this phrase to Claim 1 is found in the originally filed specification from Page 11, line 34 to Page 12, line 2.

Also by the amendments presented, Claim 1 is further rewritten to specify that the claimed method uses as a peptide substrate a synthetic serpin which is α 1-proteinase inhibitor. Support for this amendment to Claim 1 is found in the originally filed specification, for example, from Page 2, line 21 to Page 3, line 4.

Also by the amendments presented, Claim 1 is further rewritten to specify that the enzyme capable of modifying the peptide substrates is capable of cleaving the peptide substrate. Support for this amendment to Claim 1 is found in the originally filed specification at Page 9, lines 19-23.

Also by the amendments presented, Claim 3 is rewritten to correct a grammatical error, and Claim 7 is rewritten to recite particular types of samples being tested.

Also by the amendments presented, non-elected Claims 13-22 are cancelled without prejudice.

Upon entry of the claim amendments presented, Claims 1 - 12 remain in the application. No additional claims fee is due as a result of these claim amendments.

Restriction Requirement

In the instant Office Action, the previously applied restriction requirement has now been made FINAL. Accordingly, the previously withdrawn, non-elected Claims 13-22 are cancelled herein without prejudice. Applicants expressly preserve their right to pursue such cancelled, non-elected claims via one or more divisional applications.

Formal Matters

Specification Objection

In the instant Office Action, the specification has been objected to for failure to provide the required (37 C.F.R. §§1.821-1.825) sequence identifiers for certain of the peptide sequences set forth on Pages 21 and 25 of the originally filed specification. By the amendments presented herein, the appropriate sequence identifying designations are provided for these instances of listing of the CPI3 sequences. It is submitted that such amendments to the specification pages obviate this basis for objection to the specification.

Section 112 Rejections

Claims 1-12 have been rejected under 35 U.S.C. §112, First Paragraph, as allegedly being insufficiently supported by the written description with respect to the step of subjecting the peptide substrate to conditions which bring about "modification" of the substrate. The Examiner contends that the only type of "modification" adequately disclosed in the specification relates to cleavage of the peptide substrate.

By the amendments presented herein, the claim term "modification" has been replaced with the term "cleavage". It is thus submitted that the amended Claims 1-12 presented herein are fully supported by the specification teaching of the conditions suitable for bringing about cleavage of the specified peptide substrates.

Claims 1-12 have been further rejected under 35 U.S.C. §112, First Paragraph, as allegedly being insufficiently supported by the written description with respect to the breadth of the claim term "serpin reactive site loop domain". The Examiner contends that the specification teaches only cleavage of the reactive site loop domain of a specific serpin which is α 1-proteinase inhibitor and not cleavage of the reactive site loop domains of other serpins.

By the amendments presented herein, the claim term "serpin" has been replaced with the term " α 1-proteinase inhibitor". It is thus submitted that the amended Claims 1-12 presented herein are further fully supported by the specification teaching of the conditions suitable for bringing about cleavage of the α 1-proteinase inhibitor peptide substrates.

Claims 1-12 have been further rejected under 35 U.S.C. §112, First Paragraph, as allegedly being insufficiently supported by the written description with respect to the detection of the presence or absence of bacteria in the wound sample by means of detecting the presence or absence of enzymes released by the bacteria. The Examiner contends, citing WO 03/040406, that enzymes, such as metalloproteinases which also cleave the specified peptide substrates, are released from neutrophils and macrophages during wound infection/healing. The Examiner thus urges that such metalloproteinases would also be detected by the claimed method, thereby confounding use of the method to detect presence or absence of wound-infecting bacteria. Such a rejection is also respectfully traversed as it would apply to the amended claims presented herein.

In the first place, it is submitted that the specification clearly demonstrates that enzymes which are produced/secreted by a broad range of pathogenic bacteria can be detected by the method as now claimed herein. This in turn can provide an indication of the presence of the producing/secreting bacteria in the wound. In the second place, WO 03/040406 indicates at Page 1, lines 24-28 that it is the persistent presence of bacteria in a wound which results in increases in the levels of metalloproteinases. Thus to the extent that metalloproteinases present in the wound sample via this mechanism can be detected by the presently claimed method, the method of this invention still provides a useful way for detecting the presence or absence of pathogenic microorganisms.

Given the foregoing considerations, it is respectfully submitted that the bacterium detection method of the present invention is fully supported by the written description of the specification which provides the skilled artisan with all of the information and guidance necessary to practice the method as now claimed. Accordingly, continued rejection of the amended claims under 35 U.S.C. §112, First Paragraph, would be improper.

Conclusions

Applicants have made an earnest effort to place their application in proper form and to claim their invention in a manner which is fully supported by the enabling disclosure of the specification. WHEREFORE, reconsideration of this application, entry of the claim amendments presented herein, withdrawal of the specification objection and the claim rejections under 35 U.S.C. §112, and allowance of Claims 1-12 as amended, are all respectfully requested.

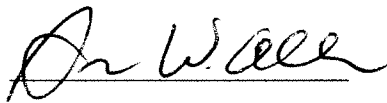
The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14964).

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It is submitted that the application is in condition for allowance. Prompt notification of allowance is respectfully solicited.

Should further issues requires resolution prior to allowance, the Examiner is requested to telephone the undersigned.

Respectfully submitted,

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